Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. (FDA–2015–D–2537) for this notice of draft guidance availability and public meeting. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Request for Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lesley DeRenzo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5161, Silver Spring, MD 20993–0002, 240–402–4612.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 28, 2015, and August 7, 2015, FDA published a notice of draft guidance availability and public meeting with a 60-day comment period and requested comments on a number of specific questions identified throughout the document. Comments on the notice of draft guidance availability and public meeting will inform FDA's development and planned implementation of a quality metrics program launched under the authority of the Federal Food, Drug, and Cosmetic Act.

FDA is extending the comment period for an additional 60 days, until November 27, 2015. The Agency believes that an additional 60-day extension of the comment period for the notice of draft guidance availability and public meeting will allow adequate time for interested persons to submit comments without significantly delaying Agency decisionmaking on these important issues.

II. Request for Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). You should annotate and organize your comments to identify the specific questions or topic to which they refer. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Dated: August 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–21149 Filed 8–25–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–2919]

In Vitro Diagnostic Testing for Direct Oral Anticoagulants; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''In Vitro Diagnostic Testing for Direct Oral Anticoagulants''. The objective of the workshop is to gain public input and to discuss analytical performance requirements for the diagnostic assessment of direct oral anticoagulants (DOACs) and the clinical circumstances under which patients receiving these agents would require testing. Specifically, this workshop aims to do the following: (1) Evaluate the impact of DOACs on traditional coagulation testing results; (2) identify clinical circumstances where testing of DOACs anticoagulant activity or concentration would be relevant; (3) discuss clinically meaningful interpretation of coagulation testing results for patients on DOACs; and (4) review the regulatory requirements for granting clearance for in vitro diagnostic devices intended for coagulation testing in patients treated with DOACs.

Date and Time: The public workshop will be held on October 26, 2015, from 9 a.m. to 5 p.m.

Location: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to: *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Contact Person: Claudia Dollins, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66 Rm. 5262, Silver Spring, MD 20993–0002, 301–796–4807, *Claudia.Dollins@fda.hhs.gov.*

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 4 p.m., October 16, 2015. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the public workshop will be provided beginning at 8 a.m.

Contact for Special Accommodations: If you need special accommodations due to a disability, please contact Susan Monahan, Center for Devices and Radiological Health, Office of Communication and Education, 301–796–5661, *susan.monahan@fda.hhs.gov* no later than October 9, 2015.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, email, and telephone number. Those without Internet access should contact Susan Monahan to register (see *Contact for Special Accommodations*). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by October 16, 2015. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after October 20, 2015. If you have never attended a Connect Pro

event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview.* (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**).

Comments: FDA is holding this public workshop to obtain information on in vitro diagnostic testing for direct oral anticoagulants. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to the public workshop is November 25, 2015.

Regardless of attendance at the public workshop, interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific questions as outlined in section II of this document, please identify the question you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at *http://www.fda.gov.* A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list).

SUPPLEMENTARY INFORMATION:

I. Background

Coagulation is the process of forming a clot to stop bleeding. Blood clotting is initiated by injury to a blood vessel resulting in the exposure of various proteins on the inner surface of the vessels. These proteins trigger the serial activation of coagulation factors that make up the coagulation cascade that culminates in the formation of the insoluble clot.

Although immediate clot formation is critical to prevent severe blood loss, excessive clot formation outside of wound healing obstructs blood flow and poses serious medical consequences. To prevent unwanted coagulation, a number of anticoagulant drugs have been developed. Historically, anticoagulation drug therapy was limited to the administration of non-specific anticoagulants, such as heparin or vitamin K antagonists, that act by inhibiting the coagulation cascade at several points. Although effective, these anticoagulants have numerous drawbacks, such as delayed onset and offset of action, a narrow therapeutic window, and interactions with food and drugs that necessitate frequent monitoring and dose adjustments. Several tests have been cleared for monitoring of patients undergoing vitamin K antagonist therapy.

A new class of DOACs has been developed in the last decade to overcome limitations of traditional anticoagulants. Thus far, FDA has approved four DOACs: PRAXADA (dabigatran), XARELTO (rivaroxiban), ELIQUIS (apixaban), and SAVAYSA (edoxaban). DOAC therapy creates a need for coagulation testing, which in turn poses new challenges.

Currently there are no FDA cleared devices for the characterization of DOAC effects on coagulation. Differences in individual responses to the drugs require laboratories to develop unique testing schemes to assess a patient's coagulation status while on DOAC regimens. Thus, the first aim of this workshop is to discuss the effect of DOACs on traditional coagulation test methods currently on the market and the impact these effects may have on patient management.

We will also examine clinical scenarios that would warrant DOAC testing. Instructions for coagulation monitoring as required for vitamin K antagonists are not specified in DOAC's instructions for use. However, in certain clinical settings assessment of DOAC-induced anticoagulation may be advantageous. The second aim of the workshop will focus on medical conditions that require coagulation testing of patients taking DOACs.

There are a limited number of strategies to assess coagulation in patients taking DOACs. We will review options for quantitative and qualitative determination of the drug effects and discuss problems related to interpretation of results. Also, we will consider the corresponding analytical performance criteria of DOAC testing required to provide reliable and informative test results.

Thus, the Center for Devices and Radiological Health plans to provide an overview of the scientific, clinical, and regulatory challenges that need to be addressed to ultimately support the development of in vitro testing for patients on DOAC regimens that would translate into clinically meaningful results.

II. Topics for Discussion at the Public Workshop

The public workshop seeks to involve industry and academia in addressing analytical performance requirements for the diagnostic assessment of DOACs. Furthermore, the workshop aims to focus on the clinical circumstances under which patients receiving these agents would require testing, including but not limited to, the following topic areas:

1. Overview of the effects of DOACs on traditional coagulation tests;
2. identification of clinical scenarios that necessitate DOAC testing;
3. interpretation of coagulation testing results for patients on DOACs; and
4. considerations for regulatory review of devices assessing the effect of DOACs on coagulation.

Dated: August 20, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–21095 Filed 8–25–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Meeting on American Indian/Alaska Native Lesbian, Gay, Bisexual, and Transgender Health Issues

AGENCY: Indian Health Service.

ACTION: Notice of meeting.

SUMMARY: The Indian Health Service (IHS) is continuing to seek broad public input as it continues efforts to advance and promote the health needs of the American Indian/Alaska Native (AI/AN) Lesbian, Gay, Bisexual, and Transgender (LGBT) community.

DATES: The meeting will be held as shown below:

1. September 11, 2015 from 12:00 p.m. EST to 2:00 p.m. EST.

ADDRESSES: The meeting location is: